#### REMARKS

The Office Action of July 1, 2009 has been carefully considered. Favorable reconsideration and allowance of the claims are respectfully requested.

# I. Claim Status and Amendments

Claims 1-45 were pending in this application when last examined. Claims 8-25 have been examined on the merits and stand rejected. Claims 1-7 and 26-45 have been withdrawn as non-elected subject matter. No claim has been allowed.

Claims 8, 11-17 and 20-25 have also been objected to

By way of the present amendment, Applicants have

amended claims 8 and 17 to incorporate the subject matter of

claims 13 and 22, respectively.

Applicants have also amended the claims in a nonnarrowing manner to address the formal matters raised in the
Office Action and to correct punctuation. Such revisions are
unrelated to patentability. The revisions are non-substantive
and they are not intended to narrow the scope of protection.
For instance, the claims have been amended to include a handof-man aspect as suggested by the examiner.

Claim 14 has been amended to depend on claim 8.

Claim 15 has been amended to depend on claim 8 or 14. Claim

16 has been amended to depend on claim 8. Claim 23 has been amended to depend on claim 17. Claim 24 has been amended to

depend on claim 17 or 23. Claim 25 has been amended to depend on claim 17. Support can be found in the claims, as filed.

No new matter has been added by the above amendments.

Claims 9-13 and 18-22 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Claims 1-8, 14-17, and 23-45 are pending upon entry of this amendment, and these claims define patentable subject matter warranting their allowance for the reasons discussed herein. Applicants request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

# II. Claim Objections

On page 4 of the Office Action, the examiner objects to claims 11, 12, 13, 14, 15, 16 and 20-25 as being in improper form because a multiple dependent claim cannot depend on another multiple dependent claim. The present amendment hereby removes the improper multiple dependencies thereby rendering the objection moot.

On page 4, the examiner separately objects to claims 8 and 17 for containing improper grammar. The present amendment overcomes this objection by removing the improper grammar for reasons which are self-evident.

Thus, the claim objections are untenable and

# III. Rejections under 35 USC 101

On page 4, claims 8-10 and 17-19 have been rejected under 35 USC 101 for being directed to non-statutory subject matter.

The present amendment obviates this rejection by amending the claims to include a hand-of-man aspect as suggested by the examiner. Withdrawal of the rejection is requested.

# IV. Indefiniteness rejections under 35 USC 112-2nd

Claims 9-10 and 18-19 have been rejected under 35 USC 112, second paragraph, for being indefinite for the reasons on pages 5-6 of the Action.

For the sole purpose of expediting prosecution and not to acquiesce to the rejection, the noted claims have been cancelled without prejudice. Thus, the present amendment renders the rejection moot.

#### V. Prior are rejections

Claims 8-9 and 17-18 have been rejected under 35 USC 102(b) as being anticipated by Imada et al. (Journal of Clinical Microbiology, Nov. 2003, pp. 5015-5021) for the reasons on pages 6-7.

Claims 8-10 and 17-19 have been rejected under 35
USC 102(b) as being anticipated by Makino et al. (Mircobial
Pathogenesis, 1998, 25: 101-109) for the reasons on pages 7-8.

These rejections are respectfully traversed.

The rejections should fall, because the cited references fail to disclose each and every element of claims 8 and 17, which are the independent claims in this application. Specifically, claims 8 and 17 relate to an isolated variant of an Erysipelothrix rhusiopathiae surface protective antigen SpaA protein or a \( \Delta \text{SpaA} \) protein, which is a shortened form of the SpaA protein, in which a portion of the SpaA protein is deleted, which is immunogenic, expressed in E. coli as inclusion bodies and has an amino acid sequence with specific amino acid substitution(s). Neither Imada et al. nor Makino et al. discloses nor even suggest such a variant as claimed in the claims 8 and 17. Tama-96 strain and Fujisawa strain are used in Imada et al. and Makino et al., respectively, without artificial amino acid substitution.

A recombinant SpaA protein or a shortened form thereof, ΔSpaA protein, including naturally occurring mutants with amino acid substitution, is usually expressed as a soluble protein. The SpaA protein and its shortened form, ΔSpaA protein, disclosed in Makino et al. are those expressed in E. coli from such naturally occurring mutants which are

supposed to be expressed as a soluble protein as is apparent from the results shown in Table 1 at page 34 of the specification. On the contrary, the claimed variant of SpaA protein and its shortened form, ASpaA protein, according to claims 8 and 17 of the present application, are defined as "an insoluble protein mutated from a soluble Erysipelothrix rhusiopathiae surface protective antigen SpaA or ASpaA protein by specific amino acid substitution" (cf. page 13, lines 10-15), have a property of being expressed as insoluble inclusion bodies to thereby facilitate recovery and purification of said protein. It should be noted that this property of being expressed as insoluble inclusion bodies is only possible when the specific amino acid substitution(s) as defined in the amended claims is/are introduced. However, neither Imada et al. nor Makino et al. disclose nor even suggest the relationship between the property of being expressed as insoluble inclusion bodies and the specific amino acid substitution(s), as claimed.

In view of the above, it should be clear that Imada et al. and Makino et al. fail to disclose each and every element of claims 8 and 17. It is well established that to anticipate a claim, a cited prior art reference must disclose or suggest each and every element of the claimed invention.

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628,

631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); and M.P.E.P., Eighth Ed., Rev. 6 (September 2007) at § 2131.

Therefore, since Imada et al. and Makino et al. fail to disclose each and every element of claims 8 and 17, the cited references cannot anticipate these claims. Accordingly, claims 8 and 17, and all claims dependent thereon, are believed to novel over Imada et al. and Makino et al. Therefore, withdrawal of the anticipation rejections is requested.

Further, Applicants believe that there is no reason/suggestion in the references to make the noted substitutions, as recited in the claims. Thus, it is believed that the claims, as amended, would never have been obvious to one of ordinary skill in the art, upon reading the cited prior art references. For these reasons, claims 8 and 17, and all claims dependent thereon, are believed to novel and non-obvious over Imada et al., Makino et al., either alone or when combined.

#### VI. Conclusion

Applicants believe that all issues raised in the Office Action have been fully addressed in a manner that should lead to patentability of the present application. Favorable consideration and allowance are respectfully requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

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